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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,639	02/02/2004	Francisco Sanchez-Madrid	27331-501CIP2A	1583

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,639	SANCHEZ-MADRID ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment to the specification of August 18, 2004 is acknowledged.

   Claims 1-108 are pending.

2. It is noted that the instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

3. The following is noted:

   Independent claims 1, 25, 44, 56, 78, 95 and 105 are drawn to methods which involve administering **"an early activation molecule antagonists/agonists/depletors"**.

   Independent claim 101 is drawn to a kit comprising **"an antibody specific for an early activation molecule".**

   The instant specification at page 4, 2nd paragraph, discloses that "**CD69, AICL and LLT1** and the nucleic acids encoding them are referred to herein as **'early activation molecules'**".

   Moreover, the instant specification at page 10, 1st paragraph discloses that **early activation molecule antagonists /agonists/depletors** encompass a variety of agents, including **"anti-CD69 antibody", "anti-AICL antibody", "anti-LLT1 antibody"** and a ***vast array of non-antibody based agents*** that antagonize, agonize or deplete early activation molecules such as "antisense", "small molecules" and "soluble receptors".

   These agonistic/antagonistic agents do **not** share *a substantial structural feature essential to a common utility*. Thus, these structurally distinct antagonists are subject to restriction, rather than election of species (as per M.P.E.P. 803.02).

   Moreover, for examination purposes, the instant claims ***will be restricted to the extent that they read on*** **the early activation molecule antagonists/agonists/depletors "anti-CD69 antibody", "anti-AICL antibody", "anti-LLT1 antibody".** Note that if non-antibody based agents are introduced into the claims they will be subject to further restriction.

   Consequently, the instant claims have been limited to methods involving administration of **the early activation molecule antagonists/agonists/depletors "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", AND** to kits comprising the **"anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody",** ***irrespective of the format of the claims***.

Restriction Requirement

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I-III. Claims 1-24, drawn to a method of treating an **unwanted immune response** in a subject comprising administering **AN AGONISTIC "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively,** classified in Class 424, subclass 130.1.

IV-VI. Claims 25-43, drawn to a method of treating a subject in **need of an increased immune response** comprising administering **AN ANTAGONISTIC "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively,** classified in Class 424, subclass 141.1.

VII-IX. Claims 44-55, drawn to a method of increasing an **immune response to a particular antigen/vaccine** comprising administering **an antigen and/or DNA** and **AN ANTAGONISTIC "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively,** classified in Class 424, subclass 144.1.

X-XII. Claims 56-77 and 105-108, drawn to a method of treating an **unwanted immune response** in a subject comprising administering **A DEPLETING "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively, and conjugates of said antibodies with a therapeutic agent, respectively,** classified in Class 424, subclasses 139.1 and 178.1.

XIII-XV. Claims 78-100, drawn to a method of treating a subject **with an early activation molecule expressing cancer** comprising administering **A DEPLETING "anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively,** classified in Class 424, subclass 153.1.

XVI-XVIII. Claims 101-104, drawn to a kit comprising an **"anti-CD69 antibody" OR "anti-AICL antibody" OR "anti-LLT1 antibody", respectively,** classified in Class 435, subclass 810.

5. Groups I-XV are different methods, which differ with respect to one or more ingredients, method steps, and/or endpoints; therefore, each method is patentably distinct. Further, the distinct ingredients, method steps, and/or endpoints require separate and distinct searches. As such, it would be burdensome to search these inventions together.

6. Groups (XVI-XVIII) and (I-XV) are directed to unrelated products and processes. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, a kit cannot be used to treat a disease, in contrast, the antibody contained therein could be used to treat a disease, however this is not what is claimed.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

8. This application contain claims directed to the following patentably distinct species of the claimed invention:

9. If applicant elects any one of **Groups I-III or X-XII**, applicant is **required to elect** one **specific pathological condition** to which the methods will be directed, for example, from among those recited in claims 16-24, such as **"rheumatoid arthritis" OR "multiple sclerosis" OR "transplant/graft rejection"**.

   These pathological conditions are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

   If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

   Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

10. If applicant elects any one of **Groups IV-VI**, applicant is **required to elect** one **specific pathological condition** to which the methods will be directed, for example, from among those recited in claims 43, such as **"immunosuppression syndrome associated with radiotherapy" OR "immunosuppression syndrome associated with chemotherapy"**.

    These pathological conditions are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

    If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

11. If applicant elects any one of **Groups VII-IX**, applicant is **required to elect** one **specific antigen/vaccine** to which the methods will be directed, for example, from among those recited in the instant specification, such as **"a melanoma vaccine" OR "a hepatitis type A vaccine"**.

These methods of increasing an immune response to a particular antigen/vaccine are patentably distinct because the antigens/vaccines are structurally different and therefore have differing abilities to provoke an immune response. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

12. If applicant elects any one of **Groups XIII-XV**, applicant is **required to elect** one **specific pathological condition** to which the methods will be directed, for example, from among those recited in claims 90, 91 and 96, such as **"cutaneous T-cell lymphoma" OR "acute myelogenous leukemia"**.

These pathological conditions are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

If applicant believes these species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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September 29, 2006